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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,340	08/31/2006	Kai Rossen	7601/88254	9531

66991 7590 12/13/2007  
LAW OFFICE OF MICHAEL A. SANZO, LLC  
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ROCKVILLE, MD 20855

EXAMINER
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LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,340	<b>Applicant(s)</b> ROSSEN ET AL.	
	<b>Examiner</b> Sun Jae Y. Loewe	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. This is a national stage application of PCT/EP05/01750. Claims 1-93 are pending in the instant application.

***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-4, 11, and 89 drawn to crystalline form of ladostigil tartrate with XRD pattern of claim 1.
- II. Group II, claim(s) 5-8 and 90 drawn to process of making ladostigil tartrate of Group I from solution of the compound in water, tetrahydrofuran, isopropanol, methylene chloride, or mixtures thereof.
- III. Group III, claim(s) 9-10 and 90 drawn to the process of making ladostigil tartrate of Group I from solution of the compound in ethanol, acetonitrile, dioxane, or mixtures thereof.
- IV. Group IV, claim(s) 11, 12, 13 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 12.
- V. Group V, claim(s) 14-21 and 90 drawn to the process of making ladostigil tartrate of Group IV.
- VI. Group VI, claim(s) 11, 22, 23 and 89 drawn to crystalline form of ladostigil tartrate with XRD pattern of claim 22.

- VII. Group VII, claim(s) 24-29 and 90 drawn to the process of making ladostigil tartrate of Group VI.
- VIII. Group VIII, claim(s) 11, 30, 31 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 30.
- IX. Group IX, claim(s) 32, 33 and 90 drawn to the process of making ladostigil tartrate of Group VIII.
- X. Group X, claim(s) 11, 34, 35 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 30.
- XI. Group XI, claim(s) 36-39 and 90 drawn to the process of making ladostigil tartrate of Group X.
- XII. Group XII, claim(s) 11, 40, 41 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 40.
- XIII. Group XIII, claim(s) 42-44 and 90 drawn to the process of making ladostigil tartrate of Group XII.
- XIV. Group XIV, claim(s) 11, 45, 46 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 45.
- XV. Group XV, claim(s) 47, 48 and 90 drawn to the process of making ladostigil tartrate of Group XIV.
- XVI. Group XVI, claim(s) 11, 49, 50 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 49.
- XVII. Group XVII, claim(s) 11, 51, 52 and 89 crystalline form of ladostigil tartrate with XRD pattern of claim 51.

- XVIII. Group XVIII, claim(s) 53, 54 and 90 drawn to the process of making ladostigil tartrate of Group XVII.
- XIX. Group XIX, claim(s) 11, 55, 56 and 89 drawn to crystalline form of ladostigil tartrate with XRD pattern of claim 55.
- XX. Group XX, claim(s) 57 and 90 drawn to the process of making ladostigil tartrate of Group XIX.
- XXI. Group XXI, claim(s) 11, 58, 59 and 89 drawn to crystalline form of ladostigil tartrate with XRD pattern of claim 58.
- XXII. Group XXII, claim(s) 60 and 90 drawn to the process of making ladostigil tartrate of Group XXI.
- XXIII. Group XXIII, claim(s) 61-65 and 89 drawn to amorphous ladostigil tartrate with XRD pattern of claim 61.
- XXIV. Group XXIV, claim(s) 66-68 and 90 drawn to the process of making ladostigil tartrate of Group XXIII.
- XXV. Group XXV, claim(s) 69 and 90 drawn to the process of making ladostigil tartrate with XRD pattern of claim 69.
- XXVI. Group XXVI, claim(s) 70 and 90 drawn to the process of making ladostigil tartrate with XRD pattern of claim 70.
- XXVII. Group XXVII, claim(s) 71 and 90 drawn to process of making ladostigil tartrate with XRD pattern of claim 71.
- XXVIII. Group XXVII, claim(s) 72 and 90 drawn to process of making ladostigil tartrate with XRD pattern of claim 72.
- XXIX. Group XXIX, claim(s) 73-75 and 90 drawn to process of making ladostigil tartrate with XRD pattern of claim 73.

- XXX. Group XXX, claim(s) 71 and 90, drawn to process, different from that of Group XXIX, of making ladostigil tartrate with XRD pattern of claim 73.
- XXXI. Group XXXI, claim(s) 80, 81 and 89 drawn to ladostigil tartrate dioxane solvate.
- XXXII. Group XXXII, claim(s) 80, 82 and 89 drawn to ladostigil tartrate acetonitrile solvate.
- XXXIII. Group XXXIII, claim(s) 80, 83 and 89 drawn to ladostigil tartrate methylene chloride solvate.
- XXXIV. Group XXXIV, claim(s) 80, 84 and 89 drawn to ladostigil tartrate ethanol solvate.
- XXXV. Group XXXV, claim(s) 80, 85 and 89 drawn to ladostigil tartrate tetrahydrofuran solvate.
- XXXVI. Group XXXVI, claim(s) 80 and 89 drawn to ladostigil tartrate solvate not covered by any of Groups XXXI-XXXV.
- XXXVII. Group XXXVII, claim(s) 86, 87 and 89 drawn to ladostigil tartrate hemihydrate.
- XXXVIII. Group XXXVIII, claim(s) 86, 88 and 89 drawn to ladostigil tartrate monohydrate.
- XXXIX. Group XXXIV, claim(s) 91-93 drawn to method of using product of Group I.
- XXXX. Group XXXX, claim(s) 91-93 drawn to method of using product of Group IV.
- XXXXI. Group XXXXI, claim(s) 91-93 drawn to method of using product of Group VI.
- XXXXII. Group XXXXII, claim(s) 91-93 drawn to method of using product of Group VIII.
- XXXXIII. Group XXXXIII, claim(s) 91-93 drawn to method of using product of Group X.

- XXXXIV. Group XXXXIV, claim(s) 91-93 drawn to method of using product of Group XXII.
- XXXXV. Group XXXXV, claim(s) 91-93 drawn to method of using product of Group XIV.
- XXXXVI. Group XXXXVI, claim(s) 91-93 drawn to method of using product of Group XVI.
- XXXXVII. Group XXXXVII, claim(s) 91-93 drawn to method of using product of Group XVII.
- XXXXIX. Group XXXIX, claim(s) 91-93 drawn to method of using product of Group XIX.
- XXXXX. Group XXXXX, claim(s) 91-93 drawn to method of using product of Group XXI.
- XXXXXI. Group XXXXXI, claim(s) 91-93 drawn to method of using product of Group XXIII.
- XXXXXII. Group XXXXXII, claim(s) 91-93 drawn to method of using product of Group XXXI.
- XXXXXIII. Group XXXXXIII, claim(s) 91-93 drawn to method of using product of Group XXXII.
- XXXXXIV. Group XXXXXIV, claim(s) 91-93 drawn to method of using product of Group XXXIII.
- XXXXXV. Group XXXXXV, claim(s) 91-93 drawn to method of using product of Group XXXIV.
- XXXXXVI. Group XXXXXVI, claim(s) 91-93 drawn to method of using product of Group XXXV.
- XXXXXVII. Group XXXXXVII, claim(s) 91-93 drawn to method of using product of Group XXXVI.
- XXXXXVIII. Group XXXXXVIII, claim(s) 91-93 drawn to method of using product of Group XXXVII.

XXXXXIV. Group XXXXXIV, claim(s) 91-93 drawn to method of using product of Group XXXVIII.

3. The inventions listed as Groups I-XXXXXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking the subject matter of Groups I-XXXXXIV is ladostigil tartrate, which is taught in the prior art (eg. see instant specification p. 1).

4. Applicant is advised that the reply to this requirement to be complete must include an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.



5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

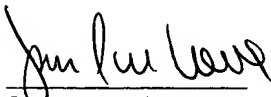
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

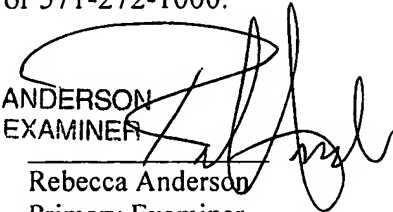
**may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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